UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

Gerald Celano, *Individually and on Behalf of All Others Similarly Situated*,	*	
Plaintiff,	*	
v.	*	Civil Action No. 1:23-cv-11125-IT
Fulcrum Therapeutics, Inc., et al.,	*	
Defendants.	*	

MEMORANDUM & ORDER

March 27, 2025

TALWANI, D.J.

Lead Plaintiff Steven Santillanes brings this securities fraud putative class action against Defendants Fulcrum Therapeutics, Inc. ("Fulcrum") and its former executives or high-level employees Bryan Stuart, Robert J. Gould, Ph.D., Christopher Morabito, M.D., and Judith Dunn, Ph.D. Plaintiff alleges Defendants misled investors about the safety of Fulcrum's leading drug candidate, FTX-6058, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder.[1] Pending before the court is Defendants' Motion to Dismiss [Doc. No. 35] Plaintiff's Amended Complaint [Doc. No. 27]. For the reasons set forth herein, the Motion is GRANTED.

[1] Plaintiff also asserted violations of SEC Regulation S-K Item 303, 17 C.F.R. § 229.303(b)(2)(ii) (2022), based on omissions, as one reason that many of Defendants' statements were false or misleading. See, e.g., Am. Compl. ¶ 91 [Doc. No. 27]. After the Supreme Court held in Macquarie Infrastructure Corp. v. Moab Partners, L.P., 601 U.S. 257, 259 (2024), that a violation of Item 303 can only support a securities fraud claim under Rule 10b-5(b) if the omission renders any statements made misleading, Plaintiff withdrew references to Item 303 and no longer asserts "pure omissions" to be securities-fraud violations. See Plaintiff's Response to Defendants' Notice at 1 [Doc. No. 44].

I. Standard of Review

In evaluating a motion to dismiss for failure to state a claim, the court assumes "the truth of all well-pleaded facts" and draws "all reasonable inferences in the plaintiff's favor." Nisselson v. Lernout, 469 F.3d 143, 150 (1st Cir. 2006). To survive dismissal, a complaint must contain sufficient factual material to "state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations . . . [f]actual allegations must be enough to raise a right to relief above the speculative level . . . ." Id. at 555 (internal citations omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

A plaintiff bringing claims sounding in fraud must also state "with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Rule 9(b) requires that a plaintiff's averments of fraud specifically plead the time, place, and content of the alleged false representation. Mulder v. Kohl's Dep't Stores, Inc., 865 F.3d 17, 22 (1st Cir. 2017). The purpose of this requirement is to "give notice to defendants of the plaintiffs' claim, to protect defendants whose reputation may be harmed by meritless claims of fraud, to discourage 'strike suits,' and to prevent the filing of suits that simply hope to uncover relevant information during discovery." Doyle v. Hasbro, Inc., 103 F.3d 186, 194 (1st Cir. 1996). The particularity requirement applies not only to actual fraud claims but also to "associated claims where the core allegations effectively charge fraud." N. Am. Cath. Educ. Programming Found., Inc. v. Cardinale, 567 F.3d 8, 15 (1st Cir. 2009).

The First Circuit has interpreted this rule to require that beyond pleading "the false statements and by whom they were made," a plaintiff must also identify "the basis for inferring scienter." N. Am. Cath. Educ. Programming Found, 567 F.3d at 13. In application, this renders a "general averment of the defendant's 'knowledge' of material falsity" insufficient. Id. (quoting Greenstone v. Cambex Corp., 975 F.2d 22, 25 (1st Cir. 1992), superseded by statute on other grounds by Private Securities Litigation Reform Act of 1995, Pub. L. No. 104-67, 109 Stat. 737). Instead, plaintiffs must put forth "specific facts that make it reasonable to believe that defendant knew that a statement was materially false or misleading." Id.

"If on a motion under Rule 12(b)(6) or 12(c), matters outside of the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56." Fed. R. Civ. P. 12(d). The First Circuit recognizes a "narrow exception" to this rule "for documents the authenticity of which are not disputed by the parties; for official public records; for documents central to plaintiffs' claim; or for documents sufficiently referred to in the complaint." See Alternative Energy, Inc. v. St. Paul Fire & Marine Ins. Co., 267 F.3d 30, 33 (1st Cir. 2001). Ultimately, the authority to consider such additional materials rests within the discretion of the trial court.

II. Background as Alleged in the Amended Complaint

A. Fulcrum Therapeutics and the Individual Defendants

Fulcrum is a small biopharmaceutical company that focuses on gene expression to treat the root cause of genetically-defined diseases. Am. Compl. ¶ 2 [Doc. No. 27]. It was founded in 2016. Id. ¶ 65. Currently, Fulcrum has two lead product candidates: Losmapimod, which targets

a disease called Facioscapulohumeral Muscular Dystrophy ("FSHD"), and FTX-6058, which is the subject of the alleged misstatements.[2]

The Individual Defendants held management positions in Fulcrum at various times during the asserted Class Period.[3] Defendant Bryan Stuart was the CEO of Fulcrum from March 2021 to January 2023. Id. ¶ 35. Defendant Robert J. Gould, Ph.D., was Fulcrum's CEO from 2016 to 2021 and from January 2023 to June 2023. Id. ¶ 36. Defendant Christopher Morabito was Fulcrum's Chief Medical Officer from May 2021 to July 2022. Id. ¶ 37. Defendant Judith Dunn, Ph.D., was the President of Research and Development at Fulcrum between 2021 and January 2023. Id. ¶ 38.

B. The Food and Drug Administration's ("FDA") Process for Approving New Drugs

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, "a drugmaker must submit research data to the FDA at two general stages of new-drug development." Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 196 (2005). In the first stage, at issue here, a drugmaker must submit an investigational new drug application ("IND") to obtain FDA authorization to administer an investigational drug or biological product to humans in a clinical study. Id.; Am. Compl. ¶ 6 [Doc. No. 27]. IND applications must include data from animal pharmacology and toxicology studies. Id. ¶ 56. This non-clinical[4] data is used to assess

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[2] According to Former Employee 2 ("FE2"), Fulcrum did not have a rich drug-development pipeline and did not have further drug trials following these two lead product candidates. Am. Compl. ¶¶ 79-80 [Doc. No. 27].

[3] The asserted Class Period is from March 3, 2022, to March 8, 2023, both dates inclusive. Am. Compl., Table of Defined Terms [Doc. No. 27].

[4] The terms "non-clinical" and "preclinical" are often used interchangeably to refer to trials that involve studies of animals or cells, not humans. Clinical trials, by contrast, involve human participants. See The Drug Development Process, Step 3: Clinical Research, U.S. Food and Drug Administration, https://www.fda.gov/patients/drug-development-process/step-3-clinical-research (last accessed March 26, 2025) ("'Clinical research' refers to studies, or trials, that are done in

whether a drug product is reasonably safe for testing in humans. Id. The application must also include information about any previous experience with the drug in humans, manufacturing information for the drug, and clinical protocols and investigator information, including detailed protocols for the proposed clinical studies, to assess whether the initial-phase trials will expose human subjects to unnecessary risks. Id.[5]

Once an IND is submitted, the FDA conducts an initial review of the IND to assure that research subjects will not be subjected to unreasonable risk. Id. ¶ 57. The FDA requires a thirty-day waiting period before a drug sponsor can begin clinical trials. Id.; 2021 Form 10-K at 22 [Doc. No. 36-3].[6] If the FDA raises concerns or questions about the non-clinical trials submitted in the IND during the thirty-day period, the drug sponsor must resolve these concerns with the FDA before clinical trials can begin. 2021 Form 10-K at 22 [Doc. No. 36-3]. Passage of the thirty-day period does not mean that the FDA has affirmatively approved the trial or trial design. Am. Compl. ¶ 57 [Doc. No. 27].

If the FDA has concerns or questions after the thirty-day waiting period, it may impose a clinical hold. A clinical hold is an order by the FDA to delay or suspend new or existing clinical trials. Id. ¶ 58. The FDA can impose a clinical hold in several circumstances, including when human subjects might be exposed to an "unreasonable and significant risk of illness or injury,"

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people."). This court uses the term "non-clinical" rather than "preclinical," except where quoting Defendants' statements, as non-clinical trials continued here after clinical trials began.

[5] After the IND is submitted, a drug sponsor may continue to conduct certain long-term non-clinical studies, including animal tests of reproductive adverse events and carcinogenicity and long-term toxicity studies. 2021 Form-10K at 22 [Doc. No. 36-3].

[6] Plaintiff did not object to this court's consideration of Fulcrum's 2021 Form 10-K, submitted by Defendants as Exhibit 3 to their motion. The document is a public record whose authenticity is not disputed by the parties, and Plaintiff refers to the document throughout his Amended Complaint.

when the clinical investigators are not qualified to conduct the investigation, or when the investigator brochure is "misleading, erroneous, or materially incomplete." Id. When a proposed study is placed on a clinical hold, the sponsor cannot recruit new subjects for testing the drug and must take any patients already testing the drug off of it. Id.

If a drug sponsor progresses through clinical development, data from animal studies and human clinical trials will eventually support the sponsor's new drug application ("NDA"). The FDA uses NDAs to determine, among other things, whether a drug is safe and effective and whether the benefits of the drug outweigh its risks, and to determine other information related to commercial marketing of the drug. New Drug Application (NDA), U.S. Food and Drug Administration, https://www.fda.gov/drugs/types-applications/new-drug-application-nda (last accessed March 26, 2025). NDAs include "full reports of investigations which have been made to show whether or not [the] drug is safe for use and whether [the] drug is effective in use." Merck KGaA, 545 U.S. at 196 (quoting 21 U.S.C. § 355(b)(1)).

C. Sickle Cell Disease

Sickle cell disease ("SCD") is a genetic disorder affecting hemoglobin, a protein in red blood cells that carries oxygen. Am. Compl. ¶¶ 43, 46 [Doc. No. 27]. Over a person's lifetime, adult hemoglobin, which is susceptible to SCD, gradually replaces fetal hemoglobin ("HbF"). Id. ¶ 46. As a result of abnormalities in adult hemoglobin, red blood cells, which are round when healthy, become hard and sticky and look like a "sickle," a C-shaped farm tool. Id. ¶ 44. These sickle cells die early, leading to a shortage of red blood cells. Id. Sickle cells also get stuck as they travel through blood vessels and clog the blood flow, which causes serious complications, such as infection, acute chest syndrome, and stroke. Id.

Until 2017, only two disease-modifying therapies for SCD were in wide use. Id. ¶ 47. Since 2017, the FDA has approved several treatments for SCD. Id. ¶ 48. Currently, several drug companies, including Fulcrum, are working to develop treatments for SCD. Id. ¶¶ 7, 49, 50.

D. Fulcrum's Initial Development of FTX-6058

FTX-6058 is an investigational treatment for SCD and other hemoglobinopathies. Id. ¶¶ 3, 67. Because HbF transports oxygen more efficiently than adult hemoglobin, FTX-6058 is designed to induce expression of HbF. Id. ¶¶ 46, 71. Fulcrum has claimed to show that FTX-6058 induces an increase in HbF and a corresponding reduction in SCD symptoms in non-clinical studies. Id. ¶¶ 5, 71. The drug does so by acting as a small molecule inhibitor of the Embryonic Ectoderm Development ("EED"), a subunit of the polycomb repressive complex 2 ("PRC2"). Id. ¶¶ 3, 4.

1. Fulcrum's Non-Clinical Studies of FTX-6058

Fulcrum began non-clinical studies of FTX-6058 as early as 2019. See 2019 Form 10-K at 6 [Doc. No. 36-21].[7] The non-clinical data for FTX-6058 had shown an increase in fetal hemoglobin levels of up to approximately 30% of total hemoglobin. Id.; Am. Compl. ¶ 72 [Doc. No. 27].

2. Fulcrum Reaches Clinical Trials of FTX-6058

In the fourth quarter of 2020, Fulcrum initiated a Phase 1 clinical trial of FTX-6058 in health adult volunteers. See 2021 Form-10K at 15 [Doc. No. 36-3]. In 2021, Fulcrum raised $46

[7] Plaintiff did not object to this court's consideration of Fulcrum's 2019 Form 10-K, submitted by Defendants as Exhibit 21 to their motion, and the court in any event finds consideration appropriate. The document is a public record whose authenticity is not disputed by the parties. It provides necessary context for understanding the company's 2021 Form 10-K, which Plaintiff refers to extensively in his Amended Complaint and which contains many of Defendants' allegedly false or misleading statements.

million in a secondary offering based, in part, on the company's success in "advanc[ing] FTX-6058 . . . into Phase 1 clinical development." Am. Compl. ¶ 69 [Doc. No. 27]. In August of that same year, the company announced results from the first clinical trial and then immediately issued a $100 million share offering. Id. ¶ 73.[8]

3. FTX-6058 Receives an Orphan-Drug Designation

In February 2022, Fulcrum received an orphan-drug designation for FTX-6058, leading to additional FDA oversight and access to FDA officials. Id. ¶ 11; 2021 Form 10-K at 15 (noting the date that FTX-6058 received the orphan-drug designation) [Doc. No. 36-3].

E. Fulcrum Makes Multiple Allegedly Misleading Statements During the First Several Months of the Class Period[9]

On March 3, 2022, Fulcrum issued a press release announcing recent business highlights and the company's Q4 and full year 2021 financial results. Am. Compl. ¶ 89 [Doc. No. 27]. In the press release, Fulcrum stated that it was "on track to initiate a Phase 1b trial with FTX-6058 in other hemoglobinopathies, including beta thalassemia." Id. ¶ 89.[10] The company also noted, in the recent business highlights section, that it had "[c]ompleted three-month preclinical

[8] Former Fulcrum employees have attested to the intense pressure Fulcrum put towards beating other drug manufacturers to FDA approval for an SCD treatment. Am. Compl. ¶ 9 [Doc. No. 27]. Former Employee 1 ("FE1"), a former Associate Director of Drug Product Development at Fulcrum from September 2020 to August 2022, asserts that competition from other drug companies led to a rush to secure FDA approval for FTX-6058 and, consequently, a reckless lack of concern for adverse FDA action against Fulcrum. Id. ¶¶ 10, 74.

[9] Plaintiff has identified 16 statements by the Defendants as false or misleading. They are incorporated throughout the discussion below.

[10] Fulcrum's Phase 1b trial involved administering the drug to SCD patients. The trial was designed to assess safety, tolerability, and pharmacokinetic and pharmacodynamic effects, including HbF protein induction. See 2021 Form 10-K at 9 [Doc. No. 36-3].

toxicology studies and initiated chronic toxicology studies to advanced FTX-6058 in multiple indications." Mar. 3, 2022 Press Release at 2 [Doc. No. 36-4].

On the same day, Fulcrum hosted an earnings call to discuss the company's Q4 2021 results. During that call, Defendant Stuart said that "[w]e are highly encouraged that our robust preclinical data and Phase 1 healthy volunteer data, both predict that we can achieve these absolute increases that will be life changing for people with sickle cell disease." Am. Compl. ¶ 97 [Doc. No. 27]. During the Q&A portion of that same call, Defendant Morabito said, "we have completed three-month tox and the three months tox gave us the continued encouragement to continue pursuing clinical development as planned." Id. ¶ 98. However, Defendant Morabito also stated that the company would not yet share the results from the ongoing non-clinical chronic toxicology studies. See Q4 2021 Earnings Call at 9 [Doc. No. 36-5].

Also on March 3, Fulcrum filed a fiscal year 2021 Form 10-K, in which the company stated that it had "also observed that FTX-6058 demonstrated robust levels of HbF elevation with no adverse effects on important cellular health markers . . . FTX-6058 was generally well-tolerated with no serious adverse events reported and no discontinuations due to treatment-emergent adverse events, or TEAEs, across all SAD [single ascending dose] and MAD [multiple ascending dose] cohorts." Am. Compl. ¶ 93 [Doc. No. 27]. In that same Form 10-K, Fulcrum explained its plans to "rapidly develop FTX-6058 for the treatment of select hemoglobinopathies," stating that Fulcrum "expected to report initial data from the trial in the second quarter of 2022" and "to initiate a Phase 1b study in the second quarter of 2022." Id. ¶ 94. The Form 10-K further stated Fulcrum's strategy included "[m]aximiz[ing] the commercial potential of [its] product candidates." Id.

On March 24, 2022, Defendant Stuart claimed at a Fulcrum event that the company had "a robust preclinical pipeline . . . ." Id. ¶ 100. In a May 9, 2022 press release, Fulcrum stated that its "clinical programs continued to make significant progress in the first quarter . . . ." Id. ¶ 104. That same day, the company tweeted from its Twitter account: "[a]s we advance two potentially life-changing therapies through clinical development while expanding our pipeline, we are well-positioned to establish Fulcrum as a leading rare disease company, supported with a strong financial foundation and a cash runway into 2024." Id. ¶ 107.

During an earnings call, also on May 9, Defendant Stuart stated that "HbF is the only mechanism that has been shown to broadly improve clinical outcomes including anemia, VOC events, pain, fatigue, and acute chest syndrome." Id. ¶ 109. On this call, Defendant Dunn also repeatedly claimed that FTX-6058 was "well-tolerated." Id. ¶ 110. When asked about the company's early 2023 timeline during the Q&A portion of the earnings call, Defendant Stuart stated: "our goal is to transition into a registrational trial as early as possible in 2023. We do believe that is consistent with what we're hearing . . . that this would be a drug because of the benefits of HbF that would be broadly utilized and has the potential to be standard of care." Id. ¶ 111. Three days later, on May 12, a Fulcrum press release reiterated that "HbF is the only mechanism that has shown the ability to broadly improve clinical outcomes for patients with SCD" and further stated that the Phase 1b study of FTX-6058 "was designed to provide proof-of-concept that FTX-6058 produces increases in HbF and could potentially be the first oral HbF inducer to address critical unmet needs in this population." Id. ¶ 113.

F. Fulcrum Hires Experts in Hematological Malignancies, Lays Off Employees, and Makes Further Allegedly Misleading Statements During the Next Few Months of the Class Period

In the summer of 2022, Fulcrum hired several experts in hematological malignancies. Id. ¶ 16. Later that same summer, Fulcrum laid off approximately 17% of its workforce. Id.

In an August 11 press release, Fulcrum quoted Defendant Stuart stating that Fulcrum had "demonstrated compelling proof of concept data for 6058 and initiated the first registrational trial for FSHD." Id. ¶ 118. Defendant Stuart stated further that Fulcrum's "strategic refocus [would] better position [it] to continue to advance [its] exciting pipeline." Id. The press release stated that Fulcrum "expect[ed] to complete enrollment in three dose cohorts by end of 2022" and was "[p]lanning to initiate registrational trial in 2023." Id. That same day, on a Q2 2022 Earnings Call, Defendant Dunn stated that Fulcrum "[had] strong preclinical evidence and now clinical evidence in sickle cell disease subjects demonstrating that 6058 produces rapid and durable HbF induction . . . . 6058 was generally well-tolerated with no serious treatment-emergent adverse events." Id. ¶¶ 121, 122. Defendant Dunn further described 6058 as having a "tremendous potential to deliver lifechanging benefits for people living with sickle cell disease." Id.

On November 8, 2022, a Fulcrum press release stated that the company had "continued [its] focus on strong clinical and operational execution." Id. ¶ 124. A company tweet on that same day stated that "[t]his third quarter for Fulcrum was focused on execution, and we've been able to make major strides in both our lead programs." Id. ¶ 127. During an earnings call that also occurred on November 8, Defendant Stuart stated that "we have two clinical programs with the potential to dramatically transform the treatment paradigm in sickle cell disease and FSHD. We are committed to moving both programs through the development and regulatory process as rapidly as possible . . . ." Id. ¶ 129. During the Q&A portion of that call, Defendant Stuart said "[w]e are going to be continuing enrollment into 2023, and that will be focused on all 3 dose cohorts. And we believe that, that is going to be able to provide sufficient data to transition into that registrational trial." Id. ¶ 130.

G. FTX-6058 Receives Fast-Track Review

In December 2022, FTX-6058 received Fast-Track Review from the FDA. Id. ¶ 17. With a Fast-Track designation, a drug sponsor may be entitled to more frequent meetings with the FDA to discuss the drug's development plan and ensure the collection of appropriate data for the drug's approval. Id. ¶ 62. The FDA bases approval for a Fast-Track designation on whether the drug fills an unmet medical need in a serious condition. Id. ¶ 63. A Fast-Track designation often leads to earlier drug approval. Id. ¶ 64.

H. Fulcrum Replaces Its CEO, Other Executives Resign, and Fulcrum Makes Further Allegedly Misleading Statements During the Next Few Months of the Class Period

On January 3, Defendant Dunn resigned. Id. ¶ 161. The next day, Fulcrum announced the replacement of its CEO, Defendant Stuart, with Defendant Gould, the former CEO. Id. ¶¶ 18, 70, 135.

Also on January 4, Fulcrum issued a press release stating, "FTX-6058 is a potential best-in-class oral HbF inducer candidate that could address critical gaps in the SCD treatment landscape." Id. ¶ 132. The press release further stated that FTX-6058 is "[g]enerally well tolerated with no drug-related treatment emergent serious adverse events and no discontinuations due to treatment emergent adverse events to date." Id.

One week later, on January 11, 2023, Fulcrum tweeted, "[w]e are entering 2023 with a tremendous amount of momentum and expect it to be a productive year for our two clinical programs: FTX-6058 for SCD, and losmapimod for FSHD." Id. ¶ 136. In January 2023, Fulcrum raised $125 million in a secondary offering, premised, in part, on the promise of FTX-6058. Id. ¶ 19.

During a February 15 conference presentation, Defendant Gould stated the following:

> FTX-6058 was generally well tolerated. There were 14 treatment emerging AEs, two of them are reported as possibly related to study drug. This was headache and lip numbness, both of which resolved spontaneously with continued drug treatment, no AEs resulted in drug discontinuation and they were all reported as mild and non-serious . . . there were no effects on blood chemistries or hematologic assessments and there are no discontinuations due to these adverse events.

Id. ¶ 139.

I. The FDA Places a Clinical Hold on the IND for FTX-6058 and Fulcrum's Stock Price Falls

On February 24, 2023, Fulcrum announced that the FDA had placed a complete clinical hold on the IND for FTX-6058. Id. ¶ 20. The announcement stated: "[t]he clinical hold was initiated by the Agency due to previously reported preclinical data. Fulcrum will suspend dosing in the Phase 1b trial of FTX-6058 and intends to work diligently with the Agency to resolve the hold as soon as possible." Id. ¶ 21.

By the close of February 24, 2023, Fulcrum's stock price fell by 56.09%, or $7.23, to close at $5.66 per share. Id. ¶ 22.

On March 9, Fulcrum announced that the FDA's clinical hold letter referenced "preclinical data previously submitted in April, October and December 2022, and non-clinical and clinical evidence of hematological malignancies observed with other inhibitors of polycomb repressive complex 2 (PRC2) . . . ." Id. ¶ 23. The company further noted that the FDA's letter stated that "the profile of hematological malignancies observed in the non-clinical studies of FTX-6058 is similar to that observed with other inhibitors of PRC2, and that hematological malignancies have been reported clinically with other PRC2 inhibitors." Id. The FDA requested that Fulcrum "further define the population where the potential benefit of continued treatment with FTX-6058 outweighs potential risk." Id.

As part of this same March 9 announcement, Fulcrum announced the sudden departure of the Chief Medical Officer, who had succeeded Defendant Morabito and had only been on the job for approximately four months. Id. ¶ 24. Following this news, Fulcrum's stock fell $1.44, or 23%, closing at $4.82 per share on March 9, 2023. Id. ¶ 25.

The clinical hold was in place for approximately six months. During this period, competing drugmakers outpaced Fulcrum in developing SCD treatments. Id. ¶ 27.

J. The FDA Lifts the Clinical Hold

The FDA lifted the clinical hold on FTX-6058 in late August 2023. Id. Even after the FDA lifted the clinical hold, Fulcrum shares traded at approximately one-third to one-half of the stock's share price at the time that Fulcrum first announced the clinical hold. Id.

K. Allegations of Scienter

Plaintiff contends that Fulcrum's clinical trial for FTX-6058 exposed patients to an unreasonable and significant risk of illness or injury and therefore did not meet the FDA's requirements for human trials. Id. ¶ 88. According to Plaintiff, FTX-6058, most other epigenetic drugs carried great safety risks to humans and can cause frequent, severe treatment-related adverse events of thrombocytopenia (low blood platelet count) and neutropenia (abnormally low count of a type of white blood cell). See id. ¶¶ 83-85. A risk is also posed because the dysregulation of PCR2 methyltransferase activity can lead to tumorigenesis in a wide range of cancers. Id. ¶ 86.

Plaintiff alleges that Defendants, but not investors, knew that FTX-6058 presented these safety concerns, and that these concerns increased the likelihood that the FDA would put a clinical hold on FTX-6058. Id. ¶ 82. An unnamed high-level employee stated that FTX-6058's toxicity and potential to cause hematological malignancies—cancers that begin in the cells of the immune system or in blood-forming tissue—was well-known within Fulcrum during the Class

Period. Id. ¶ 13. Plaintiff further alleges that Defendants were on notice at all relevant times that the FDA was focused on the dangerous side effects associated with these drugs. Id. ¶ 87.

According to Plaintiff, the Individual Defendants had the power and authority to control the contents of Fulcrum's SEC filings, press releases, and other communications. Id. ¶ 40. Because the Individual Defendants had high-level positions within Fulcrum and had access to material information not available to the public, they knew the adverse facts detailed above. Id. They also knew that the company was either not disclosing these facts or was making positive representations that were materially false and misleading. Id.

III. Discussion

To state a claim for securities fraud under Section 10(b) and Rule 10b–5, a plaintiff must sufficiently allege "(1) a material misrepresentation or omission; (2) scienter; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." In re Bos. Sci. Corp. Sec. Litig., 686 F.3d 21, 27 (1st Cir. 2012) (quoting Miss. Pub. Empls.' Ret. Sys. v. Bos. Sci. Corp., 523 F.3d 75, 85 (1st Cir. 2008)). Defendants challenge the sufficiency of the allegations as to the first, second, and sixth elements. This court addresses only the first and second elements. The central problem for Plaintiff's claims—as to both scienter and falseness or misleadingness—is Plaintiff's failure to allege significant clinical or non-clinical problems related to FTX-6058's development, let alone any awareness by Defendants of such problems.

A. Material Misrepresentation or Omission

For a Section 10(b) complaint to survive a motion to dismiss, it must allege a materially "false, or misleadingly omitted, statement of [material] fact." Constr. Indus. & Laborers Joint Pension Tr. v. Carbonite, Inc., 22 F.4th 1, 7 (1st Cir. 2021). To plead a misleading statement under the Private Securities Litigation Reform Act of 1995 ("PSLRA"), Pub. L. No. 104-67, 109 Stat. 737, a plaintiff must "specify each statement alleged to have been misleading [and] the

reason or reasons why the statement is misleading." Hill v. Gozani, 638 F.3d 40, 55 (1st Cir. 2011) (alteration in original) (quoting 15 U.S.C. § 78u-4(b)(1)). A fact or omission is material where "there is a substantial likelihood that a reasonable investor would have viewed it as significantly alter[ing] the total mix of information made available." Fire and Police Pension Ass'n of Colo. v. Abiomed, Inc., 778 F.3d 228, 240 (1st Cir. 2015) (internal quotations omitted) (alteration in original); see Operating Loc. 649 Annuity Tr. Fund v. Smith Barney Fund Mgmt. LLC, 595 F.3d 86, 92-93 (2d Cir. 2010) ("Put another way, '[a] fact is to be considered material if there is a substantial likelihood that a reasonable person would consider it important in deciding whether to buy or sell shares [of stock].'") (citations omitted).

But even where the omitted "information is material, there is no liability . . . unless there was a duty to disclose it." Roeder v. Alpha Indus., Inc., 814 F.2d 22, 26 (1st Cir. 1987). "Pure omissions" are not actionable. Macquarie Infrastructure Corp., 601 U.S. at 265. Section 10(b) only "requires disclosure of information necessary to ensure that statements already made are clear and complete." Id. at 264. Thus, Section 10(b) "do[es] not create an affirmative duty to disclose any and all material information," In re Bos. Sci. Corp., 686 F.3d at 27 (quoting Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 44 (2011)); instead, "it extends to omissions only where affirmative statements are made and the speaker fails to 'reveal [] those facts that are needed so that what was revealed would not be so incomplete as to mislead," id. (quoting Hill, 638 F.3d at 57); Thant v. Karyopharm Therapeutics Inc., 43 F.4th 214, 226 (1st Cir. 2022) ("[W]e have conclusively established that a company is not, by virtue of making some disclosures about its products, obligated to disclose all potentially interesting information."); City of Bristol Pension Fund v. Vertex Pharms. Inc., 12 F. Supp. 3d 225, 236 (D. Mass. 2014)

("A disclosure of certain facts may trigger a duty to disclose others where necessary to avoid making a misleading statement.").

Defendants' allegedly false or misleading statements fall into three general buckets:[11] (1) statements about FTX-6058's clinical results;[12] (2) statements about FTX-6058's non-clinical results;[13] and (3) statements about FTX-6058's *likelihood of approval*—that is, about the likelihood of FTX-6058 advancing through clinical trials and, relatedly, the risk of the FDA subjecting the drug to a clinical hold.[14] The court finds that Plaintiff has adequately pled that one statement in the second bucket is plausibly misleading but has not adequately pled that any statements in the other two buckets are plausibly false or misleading.

1. Statements About FTX-6058's Clinical Results

Plaintiff alleges that Defendants made several false or misleading statements about the results of Fulcrum's clinical studies of FTX-6058, such as "FTX-6058 was generally well-tolerated with no serious adverse events reported and no discontinuations due to treatment-emergent adverse events, or TEAEs, across all SAD and MAD cohorts." Am. Compl. ¶ 93 [Doc. No. 27]; see also id. ¶ 122 ("6058 was generally well-tolerated with no serious treatment-emergent adverse events."). But Plaintiff fails to allege a single known problem with FTX-6058's clinical results that would make these statements false. Plaintiff acknowledged as much at oral argument. As a result, the putatively false or misleading claims about FTX-6058's clinical

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[11] Some paragraphs of the Amended Complaint contain multiple statements, some of which fall into more than one bucket.

[12] Am. Compl. ¶¶ 93, 104, 109, 121, 122, 132, 139 [Doc. No. 27].

[13] Am. Compl. ¶¶ 93, 98, 100 [Doc. No. 27].

[14] Am. Compl. ¶¶ 89, 94, 97, 107, 109, 111, 113, 118, 124, 127, 129, 130, 132, 136 [Doc. No. 27].

results are accurate, not false, statements about the results of Fulcrum's clinical studies of FTX-6058. That is likewise true of:

- The company's statement that "HbF is the only mechanism that has been shown to broadly improve clinical outcomes . . . ." Id. ¶ 109.
- Defendant Dunn's statement that "6058 was generally well-tolerated with no serious treatment-emergent adverse events." Id. ¶ 122.
- The company's statement that FTX-6058 was "[g]enerally well tolerated with no drug-related treatment emergent serious adverse events and no discontinuations due to treatment emergent adverse events to date." Id. ¶ 132.
- The company's discussion of the two treatment-related adverse events—headache and lip numbness—that the company had observed as of February 15, 2023. Id. ¶ 139.

The recurring problem for Plaintiff is that there are no allegations that the clinical trials of FTX-6058 were anything other than "well-tolerated"—that is, that anything in the clinical results suggested that the clinical trials were unsafe for human participants. It is notable that the FDA lifted its clinical hold on FTX-6058 on August 22, 2023. See id. ¶ 152. That fact undercuts Plaintiff's repeated, and conclusory, statement that "FTX-6058 did not meet FDA requirements for continued human trials because subjects would be exposed to an unreasonable and significant risk of illness or injury." See, e.g., id. ¶ 15. It is also significant that the FDA's letter explained that it had placed a clinical hold on FTX-6058 only after observing clinical evidence of hematological malignancies with *other* PRC2 inhibitors, which suggests that the FDA did not observe any issues in the clinical studies of FTX-6058 itself. Id. ¶ 144.

Defendants did consult hematological malignancy experts while clinical studies were ongoing. See id. ¶ 116. But the inference from that allegation that Plaintiff seeks to draw, namely

that there were undisclosed defects in Defendants' clinical results, does not follow. Hiring hematological experts is not the same as observing hematological malignancies in a clinical trial. Without more detailed allegations suggesting that any such malignancies occurred or were likely, Fulcrum's decision not to discuss potential concerns about possible hematological malignancies when reporting on the results of clinical studies does not make Fulcrum's statements about the results of the clinical trials plausibly misleading.[15] See Thant, 43 F.4th at 226 (holding that a drug company's statements detailing the "most common adverse events" experienced by people taking the drug were not misleading, even though the company did not disclose serious, but less common, adverse events).

Plaintiff comes closer to alleging that there were undisclosed defects in the clinical results through the statements of confidential employees. That includes a statement by a "high-level former Fulcrum employee" indicating that "FTX-6058's toxicity and potential to cause hematological malignancies were well-known internally during the Class Period." Id. ¶ 13. It also includes statements by FE1, an Associate Director of Drug Product Development at Fulcrum from September 2020 until August 2022. See id. ¶ 74. FE1 stated that FTX-6058 "failed to meet its therapeutic goals" and "was on the toxic side." Id. ¶ 103. But these vague assertions that the company was not meeting its goals or that the drug was "on the toxic side" do not make Fulcrum's reporting of its actual clinical results plausibly false or misleading. That is especially

[15] In support of their Motion to Dismiss [Doc. No. 35], Defendants offer Exhibit 20, the FDA label for Hydroxyurea [Doc. No. 36-20] to support an argument that Fulcrum may have hired these hematological experts for an alternative reason. See Mem. to Motion to Dismiss at 17 [Doc. No. 37]. The court rejects consideration of this exhibit on a motion to dismiss (and the related argument) where the exhibit is not referenced in the Amended Complaint [Doc. No. 27] and is not a public filing along the lines of a Form 10-K. But regardless, Defendants' statements about clinical results are not false or misleading without consideration of this exhibit.

true for the statements in which Fulcrum merely reported that no adverse events had been observed during clinical trials because Plaintiff only alleges observed problems in non-clinical results. See, e.g., id. ¶ 122.

Therefore, Plaintiff has failed to allege that any of Defendants' statements about the results of the clinical studies of FTX-6058 were plausibly false or misleading.

2. Statements About FTX-6058's Non-Clinical Results

Plaintiff alleges that three statements Defendants made about the results of FTX-6058's non-clinical results were misleading: *first,* a March 2022 statement in the FY 2021 Form 10-K that, "[w]e have also observed that FTX-6058 demonstrated robust levels of HbF elevation with no adverse effects on important cellular health markers . . . ." Am. Compl. ¶ 93 [Doc. No. 27]; *second*, Defendant Morabito's statement during a Q4 2021 Earnings Call that, "we have completed three-month [preclinical] tox and the three months tox gave us the continued encouragement to continue pursuing clinical development as planned. We made no changes to our development plans based on the results from the two months tox," id. ¶ 98; and *third*, Defendant Stuart's statement that Fulcrum has "a robust preclinical pipeline . . . ." Id. ¶ 100.

Starting with the third statement, the facts alleged belie Plaintiff's suggestion that the non-clinical pipeline was not "robust." Fulcrum's non-clinical studies of FTX-6058 produced results that were sufficient for FTX-6058 to receive orphan-drug and fast-track designations, and for the FDA to authorize Fulcrum, for multiple years, to conduct clinical studies of FTX-6058—studies that are ongoing today. Id. ¶¶ 11, 62, 152. This statement is also puffery, as no reasonable investor would consider this gloss on the non-clinical studies material to an investment decision. See infra Part III.A.3 (discussing puffery).

The other two statements are a closer call. This court finds that Plaintiff has adequately alleged that one statement—the March 3, 2022 statement that Fulcrum "observed that FTX-6058 demonstrated robust levels of HbF elevation with no adverse effects on important cellular health markers"—presents a plausible jury question as to whether the statement was materially misleading. The statement was made on March 3, 2022, while the FDA's clinical hold letter referenced studies submitted to the FDA as early as April 2022. See 2022 Form 10-K at 12 ("The FDA's clinical hold referenced the data from toxicology studies in rats and dogs that we submitted to the IND in April, October, and December 2022 . . . .") [Doc. No. 36-18]. Therefore, drawing all reasonable inferences in Plaintiff's favor, pre-clinical studies had likely shown malignancies by the time of the statement, making Defendants' categorical statement about a lack of adverse effects plausibly misleading.[16]

That leaves Defendant Morabito's statement during a Q4 2021 Earnings Call, which said, in part, that "we have completed three-month [preclinical] tox and the three months tox gave us the continued encouragement to continue pursuing clinical development as planned." Am. Compl. ¶ 98 [Doc. No. 27]. Compared to the "no adverse effects" statement, this statement is less categorical. Even if there were *some* issues in the non-clinical data—a problem that made the "no adverse effects" statement misleading—, this second statement only expresses the view that the non-clinical data was adequate to justify further clinical studies of the drug. Missing from the Amended Complaint [Doc. No. 27] is any indication that there was, within Fulcrum, any kind of "widely-accepted certainty of failure" that made it plausibly misleading to simply

[16] As described below, while the Amended Complaint [Doc. No. 27] adequately alleges that the statement was objectively misleading, the allegations do not support a finding that Defendants were referring to the studies at issue in the FDA's clinical hold letter. Accordingly, Plaintiffs have failed to allege scienter as to the "no adverse effects" statement. See infra Part III.B.

state that, in the company's view, the non-clinical data supported further clinical development. See Hill, 638 F.3d at 59.[17]

Accordingly, drawing all reasonable inferences in Plaintiff's favor, only the "no adverse effects" statement is plausibly misleading.

3. Statements About FTX-6058's Likelihood of Approval

Plaintiff also alleges that Defendants made several false or misleading statements about FTX-6058's likelihood of approval. These statements were not plausibly false or misleading. Plaintiff does not allege facts suggesting that FTX-6058's likelihood of approval was materially different from what Defendants chose to disclose. Plaintiff has failed to allege the existence of any concerning results from FTX-6058's clinical studies—and thus has, necessarily, failed to allege that the drug's clinical results made FDA approval unlikely. See supra Part III.A.1. Plaintiff has also failed to allege any facts suggesting that the FDA's assessment of FTX-6058 conflicted with Fulcrum's apparent optimism about the drug's likelihood of approval prior to the FDA issuing a clinical hold, or that the hematological malignancies observed in non-clinical data made FDA approval so unlikely that Fulcrum's disclosures were misleading.

Comparing two cases is helpful here. In In re Ariad Pharmaceuticals, Inc. Securities Litigation, ARIAD executives publicly "express[ed] optimism about [a drug's] chances for approval with a 'favorable label.'" 842 F.3d 744, 753 (1st Cir. 2016). Meanwhile, the company had: (1) failed to disclose that the FDA had rejected the company's proposed label; and (2) mischaracterized the prevalence of adverse events, stating that there were "low rates of

[17] Plaintiff does allege that Mani Sundararajan, the Vice President of Research and Development at Fulcrum, opined that the company was "going down" and "needed to restructure," Am. Compl. ¶ 117 [Doc. No. 27], but there is no allegation that this opinion was widely shared within the company or even that it was based on the non-clinical studies of FTX-6058.

cardiovascular issues" even though these issues occurred in 8% of patients taking the drug. Id. The court found that these two statements were misleading. Id. Contrast Ariad with Thant, in which the court found that a drug company's statements were not misleading because the company "neither failed to disclose FDA concerns nor falsely omitted [a drug's] most-prevalent risks." 43 F.4th at 225.

This case is more like Thant than Ariad. Based on the facts alleged, the FDA never gave any indication to Defendants that their results—clinical *or* non-clinical—were concerning until the agency imposed the clinical hold. What's more, the FDA's clinical hold letter only referenced "clinical evidence of hematological malignancies" in trials of *other* drugs, suggesting that the FDA was not concerned with the results of Fulcrum's clinical studies of FTX-6058 in and of themselves, or even with the non-clinical results when viewed in isolation. Am. Compl. ¶ 23 [Doc. No. 27]. Rather, the concern, for the FDA, was what the non-clinical results for FTX-6058 indicated once judged against the non-clinical data and clinical trials for other drugs. Id. Here, there is no allegation about when the FDA had access to this data for other drugs, nor is there any allegation that the FDA realized the possible significance of the non-clinical hematological malignancies well before issuing a clinical hold for FTX-6058—and certainly not that it communicated such a concern to Defendants, such that further progression through FDA trials was considerably less likely than Defendants' public statements indicated. Instead, judging by its decision to grant FTX-6058 a fast-track designation, the FDA appeared, through the Class Period, to be in favor of FTX-6058 progressing through clinical studies. Id. ¶¶ 11, 62. That positive signal is consistent with Defendants' statements about the drug's prospects.

A few statements merit closer scrutiny because Defendants made them just before the FDA placed a clinical hold on FTX-6058. The first statement was made on January 4, 2023,

when Fulcrum issued a press release stating that "FTX-6058 is a potential best-in-class" candidate. Am. Compl. ¶ 132 [Doc. No. 27]. Second, on January 11, 2023, Fulcrum stated that it "expect[ed] it to be a productive year" for its clinical programs. Id. ¶ 136. Finally, on February 15, 2023, Defendant Gould stated that FTX-6058 was "generally well tolerated" and then reported some results from the clinical studies. Id. ¶ 139.

The last two of these statements were not plausibly misleading because these statements were apparently accurate reporting of the results of clinical studies of FTX-6058—studies that, based on the allegations in the Amended Complaint, suggested that FTX-6058 was, indeed, "well tolerated" by human subjects. As for the statement that FTX-6058 was a "potential best-in-class" candidate, that statement was sufficiently qualified—"*potential*" best-in-class candidate that "*could* address gaps"—as to be consistent even with the issuance of a clinical hold. That is particularly true given that the FDA's clinical hold letter left open the possibility that FTX-6058 was a potential candidate for FDA approval. See id. ¶ 144 ("The Agency requested that Fulcrum further define the population where the potential benefit of continued treatment with FTX-6058 outweighs potential risk.").

It is also significant that Fulcrum accompanied the allegedly misleading statements about FTX-6058's likelihood of approval with numerous disclaimers that should have tempered investors' expectations about the likelihood of the drug progressing through the FDA approval process. See, e.g., 2021 Form 10-K at 32 ("[P]roduct candidates are subject to continued preclinical safety studies, which may be conducted concurrent with our clinical testing. The outcomes of these safety studies may delay the launch of or enrollment in future clinical trials and could impact our ability to continue to conduct our clinical trials.") [Doc. No. 36-3]; Mar. 3, 2022 Press Release at 4 ("Any forward-looking statements . . . are subject to a number of risks

and uncertainties . . . includ[ing] . . . risks associated with Fulcrum's ability to obtain and maintain necessary approvals from the FDA) [Doc. No. 36-4]; Q4 2021 Earnings Call at 5 ("Please refer to our most recent filings with the Securities and Exchange Commission for a discussion of certain risks and uncertainties associated with our business," with such filings referencing risk factors such as "the timing of and our ability to submit applications for, and obtain and maintain regulatory approvals for losmapimod, FTX-6058 and any other product candidates") [Doc. No. 36-5].[18] The Thant court credited such disclosures, pointing out, with approval, that the defendant in that case "proactively couched its optimism regarding the forthcoming NDA by noting that 'accelerated approval,' as it was seeking for [its drug], 'carries a high regulatory threshold.'" Thant, 43 F.4th at 225. This court similarly finds that Fulcrum's warnings to investors about the risks associated with obtaining FDA approval support the conclusion that Fulcrum's statements about FTX-6058's likelihood of approval were not misleading.

The fact that Defendants accompanied their statements about FTX-6058's likelihood of approval with numerous disclaimers makes this case different from Matrixx, on which Plaintiff relies in support of his argument that Defendants gave a false or misleading portrayal of FTX-6058's likelihood of approval. See Opposition at 13 [Doc. No. 38]. In Matrixx, the defendant-company received reports from multiple physicians that questioned the safety of its main product, a remedy for the common cold, and was even notified by one of these physicians of a study linking the main ingredient in the company's product to the loss of smell. See 563 U.S. at

[18] Even Fulcrum's tweets included hyperlinks to press releases with disclosures conveying the potential of adverse FDA action. See Disclosures Related to Forward-Looking Statements at 16 n.11, n.12 [Doc. No. 36-2].

32. Nevertheless, the company made unqualifiedly positive statements about the company's prospects. Id. at 34-35. Moreover, in response to data suggesting the risk of a loss of smell, the company said that the data was "unfounded and misleading" and averred that the "safety and efficacy" of its products had been "well established," id. at 34-35, even though the company had evidence of a biological link between the main ingredient and the loss of smell and had done no studies of its own to disprove that link, id. at 47. On these facts, the Court held that respondents had adequately pleaded material misrepresentation. Id. at 38.

Here, however, Defendants did not make unqualifiedly positive statements about FTX-6058's prospects; the company's public filings and press releases repeatedly warned investors of the potential for adverse FDA action. This case would be more like Matrixx if Defendants had received reports of potential hematological risks from their products, and sought to publicly discredit them, but that is not what is alleged here. Instead, Defendants issued no statements addressing hematological malignancies one way or the other and repeatedly qualified their optimism about their product with acknowledgments of the potential for adverse FDA action. Matrixx is therefore inapplicable here.

Beyond the fact that the statements were not adequately alleged to be false or misleading due to Plaintiff's failure to allege problems that significantly affected FTX-6058's likelihood of approval, Defendants identify several other reasons that the statements about FTX-6058's likelihood of approval are not actionable. First, many of the allegedly misleading statements about the likelihood of approval of FTX-6058 are puffery.[19] "[U]pbeat statements of optimism

[19] Defendants are also correct that the May 9, 2022 statement that Fulcrum's "clinical programs continued to make significant progress," discussed above in Part III.A.3, is puffery. This statement is merely an adjectival gloss on the clinical results Fulcrum then immediately disclosed. See May 9, 2022 Press Release at 2 [Doc. No. 36-7].

and puffing about [a] company's prospects" are not actionable. See Thant, 43 F.4th at 223 (quoting Yan v. ReWalk Robotics Ltd., 973 F.3d 22, 32 (1st Cir. 2020)). That is because puffery does not present "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." Id. at 222 (quoting Matrixx Initiatives, Inc., 563 U.S. at 38).

"[V]ague optimism about a product's future, even when touting 'successful' or 'compelling' clinical support," is not materially misleading. Id. at 223. The category of puffery has included statements that the results of a clinical study were "an important milestone" and a "significant step," id., and statements that a high-risk robotic exoskeleton was a "breakthrough" supported by "compelling clinical data." Yan, 973 F.3d at 33; see also Fitzer v. Sec. Dynamics Tech., Inc., 119 F. Supp. 2d 12, 23 (D. Mass. 2000) ("Any statements made by the defendants relating to whether [Defendant] was 'well positioned' are ultimately no more than nonactionable 'puffing.'); LSI Design & Integration Corp. v. Tesaro, Inc., 2019 WL 5967994, at *5 (D. Mass. Nov. 13, 2019) (statement that company was 'well positioned to take this forward' was "precisely the type of statement of corporate optimism that courts routinely deem immaterial as a matter of law").

Under this standard, the following statements are inactionable puffery:

- "We are also on track to initiate a Phase 1b trial with FTX-6058 in other hemoglobinopathies, including beta thalassemia." Am. Compl. ¶ 89 [Doc. No. 27].
- "We are highly encouraged that our robust preclinical data and Phase 1 healthy volunteer data, both predict that we can achieve these absolute increases that will be life changing for people with sickle cell disease." Id. ¶ 97.

- "Our clinical programs continued to make significant progress in the first quarter . . . ." Id. ¶ 104.
- "As we advance two potentially life-changing therapies through clinical development while expanding our pipeline, we are well-positioned to establish Fulcrum as a leading rare disease company, supported with a strong financial foundation and a cash runway into 2024." Id. ¶ 107.
- "We do believe that that is consistent with what we're hearing . . . that this would be a drug because of the benefits of HbF that would be broadly utilized and has the potential to be standard of care." Id. ¶ 111.
- "This Phase 1b study was designed to provide proof-of-concept that FTX-6058 produces increases in HbF and could potentially be the first oral HbF inducer to address critical unmet needs in this population." Id. ¶ 113.
- "We demonstrated compelling proof of concept data for 6058 and initiated the first registrational trial for FSHD. Our strategic refocus will better position us to continue to advance our exciting pipeline and deliver on our unwavering commitment to patients with genetically defined rare diseases." Id. ¶ 118.
- "6058 has tremendous potential to deliver lifechanging benefits for people living with sickle cell disease." Id. ¶ 121.
- "In the third quarter, we have continued our focus on strong clinical and operational execution." Id. ¶ 124.
- "This third quarter for Fulcrum was focused on execution, and we've been able to make major strides in both our lead programs." Id. ¶ 127.

- "Currently, we have two clinical programs with the potential to dramatically transform the treatment paradigm in sickle cell disease and FSHD. We are committed to moving both programs through the development and regulatory process as rapidly as possible . . . ." Id. ¶ 129.
- "FTX-6058 is a potential best-in-class oral HbF inducer candidate that could address critical gaps in the SCD treatment landscape." Id. ¶ 132.
- "We are entering 2023 with a tremendous momentum and expect it to be a productive year for our two clinical programs: FTX-6058 for SCD, and losmapimod for FSHD." Id. ¶ 136.

Other statements, if not outright puffery, are forward-looking statements immunized by the PSLRA's safe harbor provision. See 15 U.S.C. § 78u-5. Forward-looking statements "are, generally speaking, statements that speak predictively of the future." In re Stone & Webster, Inc., Sec. Litig., 414 F.3d 187, 195 (1st Cir. 2005). Under the safe harbor provision, even fraudulent forward-looking statements do not necessarily give rise to liability under some circumstances, "including where the statement at issue is 'identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement.'" Id. (quoting 15 U.S.C. § 78u-5(c)(1)).

Defendant Stuart's statement on the Q3 2022 Earnings Call, though not puffery, is forward-looking and protected by the safe harbor. See Am. Compl. ¶ 130 ("We are going to be continuing enrollment into 2023, and that will be focused on all 3 dose cohorts. And we believe that, that is going to be able to provide sufficient data to transition into that registrational trial.") [Doc. No. 27]. The same is true for the company's statements regarding the "key components of

[its] strategy," see id. ¶ 94, its statement regarding the company's goal "to transition into a registrational trial as early as possible in 2023," see id. ¶ 111, and its statement about the company's expectation "to complete enrollment in three dose cohorts by end of 2022," see id. ¶ 118. Additionally, most of the puffery statements also include forward-looking statements protected by the safe harbor. See N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC, Inc., 537 F.3d 35, 45 n.13 (1st Cir. 2008) (When a statement refers to both to future possibilities and present facts, the safe harbor applies "only to allegations of falsehood as to the forward-looking aspects of the statement").[20] Fulcrum included the appropriate cautionary statements with its forward-looking statements such that they enjoy the protection of the safe harbor. See Chart of Disclosures [Doc. No. 36-2].[21]

Most of Defendants' statements, in all three buckets, are not adequately alleged to be false or misleading for a similar reason—namely, Plaintiff's failure to allege serious problems in

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[20] The puffery statements protected, in part, by the safe harbor are: the statement that Fulcrum's data "predict that we can achieve these absolute increases," Am. Compl. ¶ 97 [Doc. No. 27]; the statement that FTX-6058 "has the potential to be standard of care," Id. ¶ 111; the statement that FTX-6058 "could potentially be the first oral HbF inducer to address critical unmet needs," Id. ¶ 113; the statement about the company's "strategic refocus," Id. ¶ 118; the statement that "FTX-6058 is a potential best-in-class oral HbF inducer candidate," Id. ¶ 132; and the statement that Fulcrum expected it to be a "productive year," Id. ¶ 136. Many of these statements were surrounded with so much forward-looking language that a reasonable investor should have understood them to be forward-looking, notwithstanding allusions to present facts. Consider, for instance, Defendant Stuart's statements on the Q4 2021 earnings call that the company was "on track" and "anticipate[d]" seeing protein induction, see Q4 2021 Earnings Call at 6 [Doc. No. 36-5], or his statements on a Q1 2022 earnings call repeatedly emphasizing the company's "goals". See Q1 2022 Earnings Call at 13 [Doc. No. 36-8]. Regardless, any non-forward-looking parts of the statements are not misleading for the reasons discussed in other sections of this Order.

[21] The Chart of Disclosures includes a reference to Defendants' supplementary exhibits, including Exhibit 24, a copy of a Fulcrum presentation referenced in the Amended Complaint. See March 24, 2022 KOL Presentation [Doc. No. 36-24]. Plaintiff's object to this court's consideration of this Exhibit. However, the Amended Complaint refers to this same presentation, see Am. Compl. ¶ 100 [Doc. No. 27], and considering Exhibit 24 is appropriate for the limited purpose of verifying that Fulcrum included forward-looking disclaimers with the presentation.

FTX-6058's clinical and non-clinical development. As to many of Plaintiff's statements, Defendants further argue that these statements are non-actionable statements of opinion. See Mem. to Motion to Dismiss at 26-27 [Doc. No. 37].[22] In a PSLRA action, the significance of an opinion statement is that the Supreme Court has implied a slightly different standard for plaintiffs to show such a statement to be false or misleading.[23] Although opinion statements are potentially actionable, a statement in the form of an opinion will not be false or misleading merely because "an investor can ultimately prove the belief wrong," Omnicare, Inc., 575 U.S. at 186. Plaintiffs typically must show that: (1) defendants subjectively held a different view than that conveyed by the opinion statement; (2) the facts underlying the opinion statement were so obviously contrary to the opinion that it cannot be said that the opinion "fairly align[ed]" with

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[22] Defendants allege that statements in ¶¶ 89, 93-94, 97-98, 100, 104, 107, 109-11, 113, 118, 121, 122, 124, 127, 129-30, 132, and 136 of the Amended Complaint are non-actionable statements of opinion.

[23] Discussing "opinions" globally risks confusion because different kinds of statements may be made in the form of an opinion. First, there are statements prefaced by language signaling the speaker's subjective belief; See Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund, 575 U.S. 175, 179-80 (2015) (discussing the phrase "[w]e believe"). Some of Defendants' allegedly misleading statements fall into this category. See Am. Compl. ¶¶ 97, 109, 111, 124, 130, 132, 136 [Doc. No. 27]. Second, statements that include adjectives that convey subjective belief may be opinions. Here, some of Defendants' statements include such adjectives. See id. ¶¶ 93, 97, 100. Third, a statement made about a subject area in which there is room for reasonable scientific disagreement may be an opinion. This category encompasses what Defendants call "views on the interpretation of preclinical and clinical trial results." Mem. to Motion to Dismiss at 26 [Doc. No. 37]. A statement in this category might convey an "opinion"—or more commonly, a "scientific opinion"—because of uncertainty, even if the statement is not prefaced with any language suggesting that the statement is the subjective belief of the speaker. See Omnicare, 575 U.S. at 183 (explaining that the "[m]ost important" thing separating statements of fact and opinion is that the former expresses certainty while the latter does not). In the case of scientific opinions, the uncertainty arises from the fact that, based on the information and data available to the speaker, it is not possible to arrive at a single reasonable interpretation that excludes all other reasonable interpretations. Many of the Defendants' statements fall into this category. See Am. Compl. ¶¶ 89, 93, 104, 110, 113, 118, 121, 127, 129 [Doc. No. 27]. For all three kinds of statement, the mere fact that the statement is in the form of an opinion does not make it non-actionable.

those facts; or (3) defendants were significantly less informed on the matter than their opinion statement implied. Constr. Indus. & Laborers Joint Pension Tr., 22 F.4th at 7.

Plaintiff's failure to allege significant problems in FTX-6058's development, discussed at length above, amounts to a failure to show that Defendants' opinion statements did not "fairly align" with the facts underlying the statements. Plaintiff has also not shown that defendants were less informed than their opinion statements implied. Plaintiff's theory is the opposite—that "[b]ecause of their positions with Fulcrum, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading." Am. Compl. ¶ 40 [Doc. No. 27]. Plaintiff's theory does arguably speak to (1): whether the Defendants subjectively held different views from what their opinion statements conveyed. But the problem for Plaintiff here (which also undermines Plaintiff's scienter allegations) is that Plaintiff makes conclusory statements that Defendants were aware of "adverse facts" during FTX-6058's development but fails to adequately allege any such "adverse facts" that were contrary to Defendants' public pronouncements.[24]

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[24] The main exception, discussed elsewhere in this Section, concerns Plaintiff's allegations of hematological malignancies in non-clinical data, as such malignancies could allow a jury to find Defendants' "no adverse effects" statement materially misleading. See infra Part III.A.2 To the extent that the "no adverse effects" statement is a statement of scientific opinion amenable to the Omnicare framework for opinion statement, the analysis resembles this court's analysis of that same statement above: the presence of hematological malignancies meant Defendants' categorical "no adverse effects" statement plausibly fell outside the realm of reasonable scientific opinion—albeit only if one grants Plaintiff the inference that the "no adverse effects" statement referred to a wide swath of non-clinical data, rather than to three specific non-clinical studies, as discussed above. See supra Part III.A.2. Beyond the "no adverse effects" statement, Defendants' opinions regarding non-clinical data, such as the statement that the company had "robust preclinical data," Am. Compl. ¶ 97 [Doc. No. 27], are a somewhat close call because Plaintiff

For these reasons, Plaintiff has failed to allege that any of the statements about FTX-6058's likelihood of approval were plausibly false or misleading.

4. Conclusion

In sum, Plaintiff has failed to adequately allege that any of Defendants' statements were actionably false or misleading, with the exception of the "no adverse effects" statement.

B. Scienter

Scienter involves the question, did "defendants know of or recklessly disregard the falsity of [their] statements when they made them?" Quinones v. Frequency Therapeutics, Inc., 106 F.4th 177, 181 (1st Cir. 2024). Scienter is a "mental state embracing [an] intent to deceive, manipulate, or defraud." Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n.12 (1976). The First Circuit has interpreted "scienter" to encompass both a "conscious intent to defraud" and a "high degree of recklessness." ACA Fin. Guaranty Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008) (quoting Aldridge v. A.T. Cross. Corp., 284 F.3d 72, 82 (1st Cir. 2002)). In this context, recklessness is 'a highly unreasonable omission' amounting to '"an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers and sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.'" Shash v. Biogen, 84 F.4th 1, 13 (1st Cir. 2023) (quoting Mehta v. Ocular Therapeutix, Inc., 955 F.3d 194, 206 (1st Cir. 2020)).

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adequately alleges the presence of hematological malignancies in some non-clinical data. However, to use the "robust preclinical data" statement as an example, the adjective "robust" conveys subjectivity and uncertainty to a sufficient degree such that Plaintiff has failed to allege that Defendants' statement calling the non-clinical data "robust" was inconsistent with some hematological malignancies in the non-clinical data. That is especially true here because the FDA allowed clinical trials to continue, and even granted fast-track and orphan-drug designations, while in possession of the non-clinical data in question.

At the pleading stage, plaintiffs must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). "In imposing this heightened pleading standard, Congress recognized and accepted the '[i]nherent' risk of leaving 'without remedy some wrongs that discovery or trial might have disclosed.'" In re Ariad Pharm., Inc. Sec. Litig., 842 F.3d at 751 (quoting In re Bos. Sci. Corp. Sec. Litig., 686 F.3d at 32). Under First Circuit precedent, this court "must engage in 'a comparative evaluation' by weighing the 'inferences urged by the plaintiff' against 'competing inferences rationally drawn from the facts alleged.'" Shash, 84 F.4th at 13 (quoting Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 314 (2007)). "This evaluation must be done holistically, viewing the complaint in its entirety, as opposed to examining individual claims in isolation." Id. "Only where a reasonable person would deem the inference of scienter 'cogent and at least as compelling as any opposing inference of nonfraudulent intent,' will the pleading survive the PSLRA's exacting standard." Id. (quoting Tellabs, 51 U.S. at 314).

This standard is met "where a complaint 'contains clear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant[s] were aware that they were withholding vital information or at least were warned by others that this was so.'" Brennan v. Zafgen, Inc., 853 F.3d 606, 614 (1st Cir. 2017) (quoting In re Bos. Sci. Corp. Sec. Litig., 686 F.3d 21, 31 (1st Cir. 2012)). Plaintiffs may also meet this standard by "'combin[ing] various facts and circumstances indicating fraudulent intent,' including those demonstrating 'motive and opportunity . . . .'" Brennan, 853 F.3d at 614 (quoting Aldridge, 284 F.3d at 82).

As discussed above, the statements that Plaintiff alleges were false or misleading fall into three general buckets: statements about FTX-6058's clinical results, statements about the drug's

non-clinical results, and statements about the drug's likelihood of obtaining FDA approval. See infra Part III.A. Plaintiff's general theory of scienter as to these statements is that FTX-6058's orphan-drug and fast-track designations meant Fulcrum engaged in frequent discussions with the FDA about the drug's prospects, allowing the agency to be quickly apprised of issues in the development of the drug and allowing Defendants to be quickly apprised of the agency's concerns. See Opposition at 17-19 [Doc. No. 38]. Due to such discussions, Plaintiff maintains, Fulcrum hired malignancy experts and laid off staff, while nevertheless making positive announcements about the drug's trial results and likelihood of approval. Id. In response, Defendants' overarching argument is that Plaintiff has failed to allege any piece of information or negative feedback, from Fulcrum employees or the FDA, that Defendants should have been aware of and that undermined Defendants' positive, though appropriately qualified, statements about the drug. See Reply at 3-4 [Doc. No. 40].

This court agrees with Defendants: Plaintiff has failed to plead scienter. Plaintiff points to no direct evidence—such as "clear allegations of admissions, internal records or witnessed discussions"—that suggest that Defendants believed that any of their statements were misleading or at least were warned by others that this was so. Brennan, 853 F.3d at 613-614 (quoting In re Bos. Sci. Corp. Sec. Litig., 686 F.3d at 31).[25] Plaintiff's references to "the extensive communications that the Individual Defendants had with analysts and investors," and to some of the Defendants' experience and "knowledgeability," do not raise the strong inference of scienter. Am. Compl. ¶¶ 159, 160 [Doc. No. 27]. Nor do Plaintiff's references to Defendant Gould's stock

[25] As discussed further below, Plaintiff does allege that Defendants were aware of certain "adverse facts," see Am. Compl. ¶ 40 [Doc. No. 27], but fails to adequately allege what such "adverse facts" were. See infra Part III.A.3.

sales, id. ¶ 36, or to the resignations or replacement of the Individual Defendants during and after the Class Period. Id. ¶ 161.

"[W]here a complaint is devoid of any direct-evidence allegations, the indirect-evidence allegations in the complaint will need to do more work to carry the burden of raising a 'strong inference of scienter' on their own." See Shash, 84 F.4th at 16 (quoting Brennan, 853 F.3d at 615 n.8). Because "[e]ach individual fact about scienter may provide only a brushstroke," courts are to "assess each asserted fact individually before considering 'the resulting portrait' and weighing them cumulatively." Id. (quoting Local No. 8 IBEW Ret. Plan & Tr. v. Vertex Pharm., Inc., 838 F.3d 76, 81 (1st Cir. 2016)).

Plaintiff offers seven sources of indirect evidence of scienter: (1) Fulcrum's potential to engage in more frequent communication with the FDA due to FTX-6058's fast-track and orphan-drug designations; (2) the educational credentials and industry experience of Fulcrum's leadership; (3) confidential statements by former Fulcrum employees; (4) management decisions including layoffs, resignations, and hiring experts in hematological malignancies; (5) the fact that developing FTX-6058 was a "core operation" of Fulcrum; (6) the fact that Defendants allegedly held themselves out as having knowledge of the facts they misrepresented; and (7) the Individual Defendants' alleged motive and opportunity to mislead. See Opposition at 16-27 [Doc. No. 38]. This indirect evidence, taken together, fails to make a culpable inference of scienter at least as compelling as any opposing inference of nonfraudulent intent.

First, Plaintiff points to the fact that the Defendants potentially engaged in frequent communications with the FDA because of FTX-6058's orphan-drug and fast-track designations as evidence of scienter. Am. Compl. ¶¶ 62, 64 [Doc. No. 27]. The potential for frequent communications suggests that Fulcrum would have been aware of any concerns from the FDA

relatively quickly. But Plaintiff makes no allegations about specific issues discussed by the Defendants and the FDA. Even assuming the FDA expressed some concern about FTX-6058's clinical trials at some point before imposing the clinical hold, the FDA granted special designations to FTX-6058, undercutting a culpable inference of scienter.

Second, Plaintiff refers to the Defendants' credentials as evidence of scienter. See Opposition at 18-19 [Doc. No. 38]. Assuming some of Defendants' statements were scientifically unreasonable, Defendants' credentials would support a scienter inference. However, based on the facts alleged by Plaintiff, the Individual Defendants' statements were largely within the range of reasonable scientific opinion. To infer otherwise based on the FDA's clinical hold would be impermissible "fraud by hindsight." ACA Fin. Guaranty Corp., 512 F.3d at 62.

Third, Plaintiff relies on confidential statements by former employees to support a scienter inference.[26] See Opposition at 19-22 [Doc. No. 38]. The first confidential source is FE1, who was an Associate Director of Drug Product Development at Fulcrum. Am. Compl. ¶ 74 [Doc. No. 27]. That role suggests that FE1 would have had knowledge of competitors in the drug-development space, the company's focus on obtaining fast-track review, of the decision to hire hematological experts, and of the decision to lay off employees. Id. ¶¶ 75-78, 116-17. But FE1's statement that "FTX-6058 failed to meet therapeutic goals and that it was on the toxic

[26] "[W]here plaintiffs rely on confidential personal sources but also on other facts, they need not name their sources as long as the latter facts provide an adequate basis for believing that the defendants' statements were false." N.J. Carpenters Pension & Annuity Funds, 537 F.3d at 51 (quoting In re Cabletron Sys., Inc., 311 F.3d 11, 29 (1st Cir. 2002)). Confidential sources need not be named, "provided they are described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." Id.

side" is, on its face, just FE1's opinion, and is also vague about chronology. Id. ¶ 103. "Like Conan Doyle's dog that did not bark, this silence says much." Quinones, 106 F.4th at 183.

The second confidential source, FE2, occupied lower roles within Fulcrum than FE1, eventually rising to be a Computational Biologist II focused on data analysis. Am. Compl. ¶ 79 [Doc. No. 27]. That role may have made FE2 aware that only two drugs were in the company's pipeline, but FE2's statements are insufficient to suggest that any Individual Defendants shared FE2's opinion that Fulcrum lacked a "rich pipeline." Id. ¶ 80. As for FE2's statement that "adverse FDA reactions [were] not unusual at Fulcrum," this statement gives no details about what kind of adverse FDA reactions FE2 had observed, when FE2 observed them, or whether these reactions concerned FTX-6058.

The final confidential statement was by a "high-level former Fulcrum employee" who averred that "FTX-6058's toxicity and potential to cause hematological malignancies were well-known internally during the Class Period." Id. ¶ 13. Perhaps more than the other confidential statements, this statement supports a scienter inference. That said, Plaintiff does not make clear what "high-level" means, making it difficult to determine whether this employee's vantage point gave the employee inside knowledge of what was "well-known" by any of the Defendants.

Fourth, Plaintiff offers as support for a culpable scienter inference alleged company decisions that, according to Plaintiff, suggest that the Defendants knew of serious risks for FTX-6058's likelihood of approval. See Opposition at 23 [Doc. No. 38]. This includes hiring experts in hematological malignancies and laying off 17% of Fulcrum staff. Am. Compl. ¶ 16 [Doc. No. 27]. It also includes the resignations of several Fulcrum executives. Id. ¶ 161. The layoffs and resignations suggest management problems within the company and possibly financial problems as well. They also support an inference, albeit not a strong one, of possible awareness of issues

with FTX-6058, one of Fulcrum's leading potential drug products. Even so, Plaintiff fails to allege adequate facts suggesting any causal connection between the layoffs and resignations and alleged issues with FTX-6058.[27]

Fifth, Plaintiff alleges that the Defendants held themselves out as having knowledge of the facts that they misrepresented and argues that this is evidence of scienter. See Opposition at 24-25 [Doc. No. 38]. The logic of this argument is that the Individual Defendants either had, as they claimed, deep knowledge about FTX-6058's development, and were thus aware of alleged problems with the drug when making allegedly misleading statements, or the Individual Defendants lacked a factual basis to make the statements and were thus reckless with regards to the truth. Id. at 24. While this argument could be persuasive on certain facts, it is not compelling here. The statements Plaintiff cites as instances of the Individual Defendants holding themselves as "authoritative sources" on the details of FTX-6058's approval are mere reporting of the drug's development—statements that any pharmaceutical executive in the Individual Defendants' positions might make. See Am. Compl. ¶¶ 97-98, 100, 109-11, 121-22, 129-30, 139 [Doc. No. 27]. Issuing such statements did not, as Plaintiff suggests, make the Individual Defendants reckless with respect to the truth. See Opposition at 25 [Doc. No. 38].

Sixth, Plaintiff argues that developing FTX-6058 was a "core operation" of Fulcrum. See Opposition at 22-23 [Doc. No. 38]. "[T]he importance of a particular item to a defendant can support an inference that the defendant is 'paying close attention' to that item," if "that close attention would have revealed an incongruity so glaring as to make the need for further inquiry

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[27] As to the "no adverse effects" statement, discussed further below, the hiring of hematological-malignancy experts during the summer of 2022 is consistent with the notion that the company had not yet observed any adverse effects in non-clinical studies as of March 2022, when that statement was made.

obvious." Local No. 8 IBEW Ret. Plan & Tr., 838 F.3d at 84. As one of only two leading drug candidates, developing FTX-6058 was a "core operation" based on the facts alleged. Am. Compl. ¶¶ 129, 158 [Doc. No. 27]. This supports a possible scienter inference but does not, on its own, necessitate a strong inference of scienter.

Seventh and finally, Plaintiff alleges that the Defendants had a motive and opportunity to mislead.[28] See Opposition at 25-26 [Doc. No. 38]. Plaintiff adequately alleges that Fulcrum raised large amounts of money based on the promise of FTX-6058. Am. Compl. ¶ 138 [Doc. No. 27]. But "the usual concern by executives to improve financial results" does not, on its own, support an inference of scienter." Corban v. Sarepta Therapeutics, Inc. 868 F.3d 31, 41 (1st Cir. 2017) (quoting In re Cabletron Systems, Inc., 311 F.3d at 39). FE1's allegation that Mani Sundararajan, the Vice President of Research and Development, opined that the "Company situation was going down," Am. Compl. ¶ 117 [Doc. No. 27], plausibly suggests that raising money based on FTX-6058 was important to the company's survival, but it does not suggest that Fulcrum's "capital was insufficient for continued operations" or that Fulcrum would "shutter its doors unless it padded earnings by deceiving investors." Corban, 868 F.3d at 42.

As further evidence of motive, Plaintiff also alleges that Defendant Gould sold Fulcrum shares to net $92,000. Am. Compl. ¶ 36 [Doc. No. 27]. But "[f]or stock sales by corporate officials to bolster an inference of scienter, the trading must be, '[a]t a minimum, . . . unusual, well beyond the normal patterns of trading by those defendants.'" Fire & Police Pension Ass'n of Colo., 778 F.3d at 246. Plaintiff alleges that Defendant Gould sold Fulcrum shares on January 13, 2023, while in possession of material, inside information, netting $92,000, Am. Compl. ¶ 36

[28] Pleading motive and opportunity is not a requirement to establish scienter. See Tellabs, Inc., 551 U.S. at 325.

[Doc. No. 27], but that sale of 6,766 shares represented a very small fraction of his holdings, and he retained 499,864 shares after the sale. See Form 4 for Defendant Robert J. Gould at 2 [Doc. No. 36-22].[29] See Quinones, 106 F.4th at 183 (no scienter inference appropriate where defendant "did not reduce his investment in the company by enough to allow for the strong inference of scienter claimed by plaintiffs). Moreover, "'even unusual sales by one insider do not give rise to a strong inference of scienter' when other insiders ha[ve] not engaged in suspicious trading during the class period." Quinones, 106 F.4th at 183 (quoting N.J. Carpenters Pension & Annuity Funds, 537 F.3d at 56).

Considering Plaintiff's indirect evidence in its totality, the most compelling inference is not a culpable scienter inference. Instead, it is as follows: Defendants conducted many kinds of non-clinical studies over several years, beginning at least as early as 2019. See 2019 Form 10-K at 6 [Doc. No. 36-21]. By March 3, 2022, the start of the Class Period, most of these non-clinical studies had shown no adverse effects, or at most minimal adverse effects, on important cellular health markers. At the start of the Class Period, Fulcrum had only recently initiated chronic toxicology studies in animals, after successfully completing the shorter-term three-month non-clinical toxicology studies. See Mar. 3, 2022 Press Release at 2 [Doc. No. 36-4]. Fulcrum submitted early data from these chronic toxicology studies to the FDA in April 2022, and submitted more data from the studies in October and December of the same year.

[29] These sales were effected pursuant to a Rule 10b5-1 trading plan adopted by Defendant Gould on September 7, 2022. Id. Against Plaintiff's objections, this court will consider Defendant Gould's Form 4 because it is a public securities filing whose authenticity is not disputed and because it reliably documents the stock sale that Plaintiff references in the Amended Complaint [Doc. No. 27].

At some point in 2022, Defendants recognized malignancies in the non-clinical data from these chronic toxicology studies, possibly based on feedback from the FDA. Defendants decided to hire experts in hematological malignancies during the summer of 2022, shortly after observing these malignancies for the first time in non-clinical studies. Nevertheless, Defendants continued to feel optimistic about FTX-6058's likelihood of approval because the FDA granted FTX-6058 fast-track review while in possession of the non-clinical data. Given that the FDA has already approved at least one EED inhibitor that showed "secondary malignancies and preclinical toxicology," Am. Compl. ¶ 84 [Doc. No. 27], Defendants believed that FTX-6058 was still on track for approval. In early 2023, the FDA imposed a clinical hold, but only after reviewing the April, October, and December 2022 data and comparing it with data from trials of other drugs. Defendants announced the clinical hold shortly thereafter—a hold the FDA later lifted.

Plaintiff's core problem with respect to scienter is that Plaintiff fails to allege that any non-clinical results, clinical results, or FDA feedback prior to the clinical hold letter seriously affected FTX-6058's likelihood of approval. Plaintiff does not allege that the FDA identified any problem with Fulcrum's clinical studies of FTX-6058, nor that the Agency raised concerns about FTX-6058's likelihood of approval before issuing a clinical hold. To the contrary, the FDA, which possessed the allegedly concerning non-clinical data for over a year,[30] let clinical trials continue, granted FTX-6058 an orphan-drug designation, and put the drug on fast-track review. Id. ¶¶ 11, 62. That fast-track designation, at a minimum, indicated the FDA's view that FTX-6058 had the potential to "show some advantage over available therapy." See 21 U.S.C. § 356(b); In re Biogen Idec, Inc. Sec. Litig., 2007 WL 9602250 at *13 (D. Mass. Oct. 25, 2007),

[30] The clinical hold letter referenced preclinical data submitted in April 2022, but the FDA did not issue the clinical hold until around February 24, 2023. See Am. Compl. ¶ 23 [Doc. No. 27].

aff'd sub nom. N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc., 537 F.3d 35 (1st Cir. 2008) ("The fact that the FDA approved 'fast-track' certification of the drug while in the possession of such data undermines the plaintiffs' reliance on the presence of such adverse events as proof that the drug was unsafe to place on the market."). Furthermore, "while not a section 10(b) liability shield," the FDA's decision to allow continued clinical trials and, eventually, to lift the clinical hold does not make for a strong scienter inference. Shash, 84 F.4th at 16.

The FDA's positive signals and the lack of allegations of specific negative feedback from the FDA make this case quite unlike In re Transkaryotic Therapies, Inc. Securities Litigation, 319 F. Supp. 2d 152 (D. Mass. 2004), on which Plaintiff attempts to rely to establish scienter. See Opposition at 18 [Doc. No. 38]. In Transkaryotic, a drug company made misleading statements about the efficacy of its drug product *after* the FDA had sent the defendants a letter stating, "bluntly and at length," that the company had "failed to demonstrate efficacy." Transkaryotic, 319 F. Supp. 2d at 156. In the present case, on the other hand, Plaintiff does not allege any specific issues that the FDA raised with the Defendants before the FDA issued its clinical hold. Instead, this case is more like Leavitt v. Alnylam Pharmaceuticals, Inc., in which the court faulted plaintiffs' scienter allegations for failing to allege that the FDA expressed to Defendants any disapproval of the drug at issue. See 525 F. Supp. 3d 259, 266 (D. Mass. 2021).

Plaintiff has not alleged that the FDA expressed to Defendants an inclination to take adverse action regarding FTX-6058. The First Circuit has found that a plaintiff failed to raise a strong inference of scienter even where the defendant, a medical device company, waited months to disclose that it had received a warning letter from the FDA notifying the company that its device was misbranded and threatening sanctions absent corrective action. See Yan, 973 F.3d at

29. The court averred that it was still reasonable for the company not to disclose the warning letter where defendants "believed they could still meet the FDA's requirements." Id.

Here, Plaintiff alleges only that "Defendants were, at minimum, on notice that (i) FTX-6058 belonged to a class of drugs with increased potential to cause cancers, including hematological malignancies and (ii) as a result, the FDA was focused on the dangerous side effects associated with of those drugs." Am. Compl. ¶ 87 [Doc. No. 27]. If the FDA warning letter in Yan was not enough to raise the strong scienter inference, the allegation that Defendants were aware of the FDA's focus on hematological malignancies is not enough, either.

As discussed above, a jury could find the March 3, 2022 "no adverse effects" statement that Fulcrum "observed that FTX-6058 demonstrated robust levels of HbF elevation with no adverse effects on important cellular health markers" materially misleading because of the possibility that Defendants knew of hematological malignancies in non-animal clinical toxicology studies when this statement was made. See id. ¶ 93; infra Part III.A.2 (explaining why a jury could find the statement materially misleading). The court therefore addresses scienter as to this statement in greater detail.

The difficulty for Plaintiff in showing scienter as to this statement is that Plaintiff has not alleged facts showing that Defendants were referencing data in which malignancies were observed. In a press release from March 3, 2022 (the same day that Fulcrum released the 2021 Form 10-K), Fulcrum shared, in the recent business highlights section, that it had "[c]ompleted three-month preclinical toxicology studies and initiated chronic toxicology studies to advanced FTX-6058 in multiple indications." Mar. 3, 2022 Press Release at 2 (emphasis added) [Doc. No. 36-4]. Defendant Morabito, on the same day that the "no adverse effects" statement was made, reported that the company did not "have any new findings to share" for this ongoing "preclinical

chronic tox for the 6058 program." See Q4 2021 Earnings Call at 9 [Doc. No. 36-5]. Given that the non-clinical chronic toxicology studies were ongoing in March 2022, and given the frequent communication between Fulcrum and the FDA, it was most likely data from these non-clinical chronic toxicology studies in animals that the FDA referenced in its later clinical hold letter.[31]

If the "no adverse effects" statement referred to data from these same non-clinical chronic toxicology studies, a culpable scienter inference is compelling because Plaintiff had adequately alleged that Defendants had observed malignancies in such data when the "no adverse effects" statement was made. But the statement likely referred to three other studies—one involving treatment in differentiated primary human CD34+ cells (a cell study), one comparing the effect of FTX-6058 in CD34+ derived cells relative to the effects of hydroxyurea (a cell study), and one studying FTX-6058 in a mouse model (an animal study). See 2021 Form 10-K at 16-17 [Doc. No. 36-3].[32]

It is unlikely that any of these studies were the ones mentioned in the FDA's hold letter, in which Defendants had plausibly observed malignancies as of March 2022. As stated above, Defendant Morabito reported that the company did not have new findings to share about the chronic toxicology studies in animals, so it is unlikely that the "no adverse effects" statement

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[31] At oral argument, Defendants argued that the "no adverse effects" statement referenced only cellular studies. If that were true, the "no adverse effects" statement could not have been referring to the animal toxicology studies referenced in the FDA's clinical hold letter, which would be fatal to the culpable scienter inference. But for the reasons described herein, the "no adverse effects" statement was likely referencing both animal and cellular studies.

[32] The portion of the Form 10-K describing the studies of concern does not include the "no adverse effects" statement but does include a similar statement that the company observed "minimal adverse effects on important cellular health markers." See 2021 Form 10-K at 16-17 [Doc. No. 36-3]. But the "minimal adverse effects" and "no adverse effects" were likely referencing the same studies, as the language in the discussions in which these statements appear is largely the same, including, for instance, identical references to "CD34+ derived cells". Compare 2021 Form 10-K at 8 [Doc. No. 36-3], *with* id. at 16-17.

made on that same day referred to such studies. See Q4 2021 Earnings Call at 9 [Doc. No. 36-5]. Moreover, the chronic toxicology studies in animals were likely ongoing as of March 2022 and had only recently been initiated. Yet, Fulcrum had included the "no adverse effects" statement in its Form 10-Ks since at least 2019, years before the company conducted the animal toxicology studies referenced in the clinical hold letter. See 2019 Form 10-K at 5 [Doc. No. 36-21]. While that suggests that the "no adverse effects" statement was possibly a sloppy copy-paste mistake from an earlier Form 10-K, it also indicates that the statement was not referencing the later-stage nonclinical studies in which Defendants had plausibly observed malignancies.

Regardless, it is unlikely that investors would view this sloppy copy-paste as "significantly alter[ing] the total mix of information made available," Fire & Police Pension Ass'n of Colo., 778 F.3d at 240 (internal quotations omitted) (alteration in original). The 2021 Form 10-K noted both "no adverse effects" and "minimal adverse effects" in reference to the same non-clinical studies, so a reasonable investor would not have interpreted the "no adverse effects" statement to mean the results presented no concerns whatsoever. Defendants could have been more cautious. The distinction between "no adverse effects" and "minimal adverse effects" could be the difference between an actionable securities fraud claim and a non-actionable claim. See Shash, 84 F.4th at 14 ("[I]t follows that Defendants must have known that their failure to disclose said data risked misleading investors precisely because of what the "all data" statement represented—that their 'data [was] all consistent with' 'need[ing] to get to the higher dose' of aducanumab."). However, the "no adverse effects" statement falls short of an "extreme departure from the standards of ordinary care" that would justify a culpable scienter inference. Id. at 13 (quoting Mehta, 955 F.3d at 206).

Therefore, Plaintiff has failed to allege a strong inference of scienter as to any statements, including the "no adverse effects" statement.

C. The Section 20(a) Claim

Plaintiff asserts claims for control person liability pursuant to Section 20(a) of the Exchange Act against the Individual Defendants. Section 20(a) imposes joint and several liability on any person who, "directly or indirectly, controls any person liable" under Section 10(b) and Rule 10b-5. 15 U.S.C. § 78t(a). Section 20(a) "only creates liability derivative of an underlying securities violation," meaning plaintiffs must show a Rule 10b-5 violation by the controlled entity to prevail on a Section 20(a) claim. ACA Fin. Guaranty Corp., 512 F.3d at 67-68. Accordingly, Plaintiff's failure to show scienter as to any statements is fatal to his Section 20(a) claim as to these statements.

D. Leave to Amend

Plaintiff requested in his briefing that if the court grants Defendants' motion in whole or in part, that he be allowed to amend his complaint. Opposition at 30 [Doc. No. 38]. Here, Plaintiff did not promptly seek leave to amend his complaint to address any deficiencies after reviewing Defendants' Motion to Dismiss and has not suggested any basis for waiting to amend his complaint until after that Motion is decided. See ACA Fin. Guaranty Corp., 512 F.3d at 56 ("Plaintiffs may not…wait in the wings" to see whether the district court finds their first complaint adequate); see also City of Mia. Fire Fighters' & Police Officers' Ret. Tr. v. CVS, 46 F.4th 22, 38 (1st Cir. 2022) ("[T]here is no basis for contending that in this case the grounds for dismissal were somehow a surprise."). Nor did he submit a proposed second amended complaint with his request or articulate what additional facts would be alleged in a proposed amendment. As a result, plaintiff's request for leave to amend is denied.

IV. Conclusion

For the foregoing reasons, Defendants' Motion to Dismiss is GRANTED.

IT IS SO ORDERED

March 27, 2025

/s/ Indira Talwani
United States District Judge